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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,866	04/02/2001	Frank Austrup	790076.403US	5636

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06/10/2003

Seed
701 Fifth Avenue Suite 6300
Seattle, WA 98104-7092

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/10/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,866

Applicant(s)

AUSTRUP ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10 and 22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 10 and 22 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed April 2, 2003 in Paper No. 13 is acknowledged and has been entered. Claims 8, 9, and 11-21 have been canceled. Claims 1-7 and 10 have been amended. Claim 22 has been added.

2. Claims 1-7, 10, and 22 are pending in the application and are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

3. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed December 4, 2002 (Paper No. 11) have been withdrawn.

Claim Objections

4. Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4 and 5 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rye, et al (*American Journal of Pathology* **150**: 99-106, 1997) for the reason set forth in the Office action mailed December 4, 2002 (Paper No. 11).

Applicants have traversed this ground of rejection arguing that the prior art does not anticipate the claimed invention, because the prior art does not teach all the limitations of the claims.

Applicants' arguments have been carefully considered but not found persuasive for the following reasons:

Rye, et al teaches a method for isolating disseminated tumor cells from blood, bone marrow, ascitic or pleural fluids, and enzyme-digested tissue biopsies. Although Rye, et al does not explicitly refer to the isolated tumor cells as disseminated tumor cells, it is clear that the tumor cells from the blood and bone marrow of the patients had disseminated from breast cancers or malignant melanomas, as the tumor cells were isolated from anatomical site distant from the anatomical site of the primary tumor. Rye, et al teaches passing a cell-containing body fluid or part thereof through a screen having pores of a width of 20 microns, or μm . More particularly, Rye, et al teaches samples were prepared by subjecting peripheral blood and bone marrow specimens to Lymphoprep™ density gradient centrifugation, a process which separates the cellular components of the specimens from non-cellular components. The cell pellets were resuspended in a suspension medium, namely Dulbecco's minimal essential medium. The suspension of cells was passed through a 20-micron nylon microfilament filter and obtaining a retained fraction of cells comprising the disseminated tumor cells. Although Rye, et al teach an additional step, namely incubating the suspension of cells with a primary antibody bound to magnetic beads and magnetically separating tumor cells bound by the antibody from other cells not bound by the antibody, was performed before filtration, the specification teaches that such a step can be performed before filtration at page 13, lines 25-32.

Accordingly, all the limitations of the claims are met by the teachings of Rye, et al.

7. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,265,229-B1 for the reason set forth in the Office action mailed December 4, 2002 (Paper No. 11).

Applicants have traversed this ground of rejection arguing that the prior art does not anticipate the claimed invention, because the prior art does not teach all the limitations of the claims.

Applicants' arguments have been carefully considered but not found persuasive for the following reasons:

US Patent No. 6,265,229-B1 ('229) teaches a method for isolating micrometastatic tumor cells from various bodily fluids, including blood, bone marrow, and effusions, which comprises filtering a suspension of cells through a porous membrane having preferably 20 micron pores and obtaining a retained fraction of cells comprising the disseminated tumor cells. Although '229 does not explicitly refer to the isolated tumor cells as disseminated tumor cells, it is clear that in practicing the disclosed methods, the tumor cells isolated from the blood or bone marrow of the patients diagnosed with non-hematological malignancies, i.e., breast cancer, would have to have disseminated from the anatomical site of origin, or the primary tumor. '229 refers to these cells as micrometastatic; and it is noted that similarly the specification uses the term "micrometastasized" to refer to a subgenus of disseminated cancer cells at page 7, lines 3-7). In addition, '229 teaches that the specimens of blood and bone marrow may be prepared by density gradient centrifugation, providing the example of Lymphprep™ density gradient centrifugation, followed by resuspension in a resuspension medium.

Accordingly, all the limitations of the claims are met by the teachings of '229.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

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slr

June 3, 2003

